2009 H1N1 Influenza
Updated Key Points
October 20, 2009

2009 H1N1 Influenza Vaccine

- Every Friday, CDC will post updated 2009 H1N1 vaccine supply and distribution data on the web at www.cdc.gov/h1n1flu.

- Each Thursday, CDC will share vaccine supply and distribution data with state and local public health partners for their awareness prior to the data being posted to the web and discussed in CDC's Friday press briefings. We hope this will help our state and local partners prepare for local press activity. The data include weekly aggregate totals of doses allocated, ordered, and shipped through Wednesdays. A breakdown of doses shipped by project area is also included. r

- **(Updated)** As of Monday, October 19th, there were a total of 10,808,200 million doses ordered.

- **(Updated)** As of Monday, October 19th, a total of 12,837,600 doses were available for ordering. Of those available doses, 6,841,900 million doses were injectable (flu shots) and 5,995,700 million were LAIV (nasal spray vaccine).

- All states and the District of Columbia have placed orders for vaccine, and more orders are expected daily.

- The vaccine situation changes rapidly – throughout each day, vaccine is being shipped from the vaccine manufacturers to McKesson distribution centers; orders are coming into McKesson; orders are being processed and shipped; and vaccine is arriving in thousands of places across the country.

- Initial doses of 2009 H1N1 "flu shot" were shipped the week of October 12th, with additional doses scheduled for shipment each week.

- First doses of 2009 H1N1 vaccine were administered outside of the clinical trials on Monday, October 5, 2009.

- McKesson, the distributor for the 2009 H1N1 vaccine, is increasing the number of delivery sites from 90,000 to 150,000**.**

- 2009 H1N1 vaccination has begun but initial supplies are small. More doses are expected for shipment each week. We ask members of the public who want to receive this vaccine to be patient as this program expands and more vaccine becomes available. There will be enough vaccine available for anyone who wishes to receive it.

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- The vaccine development process is complex and forecasting how much vaccine will be available at a certain time is challenging and amounts will vary from week to week. Millions of doses of vaccine are in the pipeline and federal, state and local public health authorities are working hard to get vaccine out to the public as soon as we receive it.

- We had to choose between waiting to distribute vaccine until we had large quantities ready to be shipped versus distributing limited quantities of the vaccine sooner. We chose the latter knowing that it would create some challenges and frustrations (for our public health partners in the states, providers, and the public), but also knowing that it would allow us to start protecting people against this disease as soon as possible.

- Thus, we only have small amounts of vaccine for states to order at the moment. Given this situation, states will initially be conducting very targeted vaccination efforts that take into consideration their local situation with 2009 H1N1 disease.

- It is important to also keep in mind that there will be lag times between states placing orders and vaccine actually being distributed (we are not cutting corners in terms of steps like quality control checks) - and any number of things can create lag times between time of distribution to states and when vaccine actually arrives in provider offices or clinics.

- This vaccine program is a massive and challenging undertaking and is being carried out at a time when state and local health departments have experienced severe budget cuts. There will likely be bumps along the way, but we are optimistic that we will achieve our goal of making the 2009 H1N1 vaccine available to all of those who need and want it.

- On September 21, 2009, The National Institute of Health (NIH) announced that early results from a trial testing a 2009 H1N1 influenza vaccine in children look promising. Preliminary analysis of blood samples from a small group of trial participants shows that a single 15-microgram dose of a non-adjuvanted 2009 H1N1 influenza vaccine – the same dose that is in the seasonal flu vaccine – generates an immune response that is expected to be protective against 2009 H1N1 influenza virus in the majority of 10- to 17- year-olds within eight to 10 days following vaccination. These results are similar to those recently reported in clinical trials of healthy adults. Younger children generally had a less robust early response to just one dose of the vaccine.

- Children younger than 10 years should receive two doses of 2009 H1N1 flu vaccine. This is slightly different from CDC's recommendations for seasonal influenza vaccination which state that children younger than 9 who are being vaccinated against influenza for the first time need to

receive two doses. Infants younger than 6 months of age are too young to get the 2009 H1N1 and seasonal flu vaccines.

- CDC recommends that when two doses of flu vaccine are required, the two doses should be separated by 4 weeks. However, if the second dose is separated from the first dose by at least 21 days, the second dose can be considered valid.

- The national vaccine program is voluntary. Those interested in vaccination for themselves or their children will receive accurate information about 2009 H1N1 influenza vaccine and the vaccine's benefits and risks so they can make an informed decision.

- A report in the August 21, 2009, *Morbidity and Mortality Weekly Report* (MMWR) provides official recommendations by CDC's Advisory Committee on Immunization Practices (ACIP) regarding the use of vaccine against 2009 H1N1 influenza.

- The guiding principle of these recommendations is to vaccinate as many persons as possible as quickly as possible with an emphasis on vaccinating certain target groups with initial doses of vaccine.

- These recommendations include:

  1) Identify five initial target groups for vaccination efforts comprising an estimated 159 million persons (pregnant women, persons who live with or provide care for infants younger than 6 months, health care and emergency medical services personnel, children and young adults aged 6 months through 24 years, and persons aged 25 through 64 years who have medical conditions that put them at higher risk for influenza-related complications),

  2) Establish a priority subset of persons within the initial target groups in the event that initial vaccine availability is unable to meet demand, and

  3) Provide guidance on use of 2009 H1N1 vaccine in other adult population groups as vaccine availability increases.

- The recommendations are broad and allow for flexibility to accommodate local variability in vaccine needs and demands. Providers should be aware of and follow any additional guidance provided by their state or local health departments. If no additional guidance is provided at the state or local level, providers should vaccinate among the initial target group populations on a first come, first serve basis.

- Simultaneous administration of inactivated vaccines against seasonal and the 2009 H1N1 influenza viruses is permissible if different anatomic sites are used (for example, one vaccine in each arm).

2009 H1N1 Influenza Vaccine Safety

General H1N1 Vaccine Safety

- The 2009 H1N1 influenza vaccines have not been associated with any unexpected adverse events (or possible side effects). In addition, the 2009-2010 seasonal influenza vaccines also have not been associated with any unexpected adverse events (or possible side effects).

- The 2009 H1N1 influenza vaccine have a similar safety profile as seasonal flu vaccines, which have very good safety track records.

- CDC expects that any serious side effects following vaccination with the 2009 H1N1 influenza vaccine would be rare.

- The types and frequencies of side effects from the 2009 H1N1 vaccine will likely be similar to those experienced following seasonal influenza vaccines which are mild, localized reactions.

Vaccine Safety Monitoring

- CDC and its partners are using several systems to monitor the safety of 2009 H1N1 influenza vaccine. Two primary systems that are in use are the Vaccine Adverse Event Reporting System (VAERS), which is jointly operated with FDA, and the Vaccine Safety Datalink (VSD) Project.

- Additionally, CDC is conducting surveillance of adverse events through partnerships with other federal agencies, professional organizations, and academic institutions.

- CDC and FDA closely monitor the safety of all vaccines licensed for use in the United States, including seasonal influenza vaccines, in cooperation with state and local health departments, health care providers, and other partners. Additional special monitoring of the 2009 H1N1 vaccine is occurring to assure that any rare side effects are detected as soon as possible.

- Vaccine safety monitoring is a complex process that uses both active and passive surveillance.

- Vaccine safety monitoring includes reviewing adverse events reported by providers, manufacturers, people who were vaccinated or their caregivers,

and comparing the rate of these adverse events to the background rates (the rates at which they normally occur in the population).

  - An adverse event following immunization is a medical incident that occurs after someone receives an immunization.

  - Adverse events may be coincidental (meaning occurring around the same time but not related to vaccination) or caused by vaccination.

  - Adverse events can be reported by providers, manufacturers, people who were vaccinated or their caregivers.

- The purpose of vaccine safety monitoring is timely identification of any clinically significant adverse events following immunization, as well as to provide timely information to the public, vaccine providers, public health officials, and policy makers.

- As with all vaccines licensed for use in the United States, any problems detected with this vaccine will be reported to health officials, health care providers, and the public, and needed action will be taken to ensure the public's health and safety.

Adjuvants

- Some vaccines contain "adjuvants," which are ingredients that help boost the vaccine's potency. As a result, a smaller amount of vaccine is needed per person, and therefore, the vaccine supply can be used to reach more people.

- Only unadjuvanted influenza (flu) vaccines will be used in the United States during the 2009-10 flu season.

- This includes all of the 2009 H1N1 and seasonal influenza vaccines that will be available for children and adults in both the injectable (flu shot) and nasal spray formulations. None of these influenza vaccines that will be used in the U.S. during the 2009-10 season will contain adjuvants.

- Studies of 2009 H1N1 influenza vaccines with adjuvants are being conducted to determine if 2009 H1N1 influenza vaccines with adjuvants meet safety and efficacy requirements for use in the United States.

Thimerosal

- Thimerosal is a mercury-based preservative that is used in some influenza vaccines to keep them free from contamination of microorganisms.

- The 2009 H1N1 influenza vaccine is being manufactured in several formulations.

    - Several vaccine manufacturers will be producing some of the 2009 H1N1 influenza vaccine in single-dose units, which will not require the use of thimerosal as a preservative.

    - The live-attenuated version of the vaccine, which is administered intranasally (through the nose), is produced in single-units and will not contain thimerosal.

    - Some vaccine will come in multi-dose vials and will contain thimerosal as a preservative, as is the case with seasonal influenza vaccines in multi-dose vials.

- Multi-dose vials of seasonal influenza vaccine contain thimerosal to prevent potential contamination after the vial is opened. Seasonal flu vaccines that do not contain thimerosal also are available.

Guillain-Barré syndrome (GBS) (Updated)

- Guillain-Barré syndrome (GBS) is a medical condition in which the body damages its own nerve cells, causing muscle weakness and sometimes paralysis.

- It is not fully understood why some people develop GBS, but it often occurs following infection. It is believed that stimulation of the body's immune system may play a role in its development.

- The infection that most commonly precedes GBS is caused by a bacterium called *Campylobacter jejuni.* Influenza virus infection has also been associated with GBS.

- Most people who develop GBS fully recover, but in some cases, death can result, usually from difficulty breathing.

- In 1976, there was a small risk of GBS following influenza (swine flu) vaccination (approximately 1 additional case per 100,000 people who received the swine flu vaccine). That number of GBS cases was slightly higher than the background rate for GBS. Since then, numerous studies have been done to evaluate if other flu vaccines were associated with GBS. In most studies, no association was found, but two studies suggested that approximately 1 additional person out of 1 million vaccinated people may be at risk for GBS associated with the seasonal influenza vaccine.

- FDA and CDC and several partners will be closely monitoring reports of serious vaccine adverse events, including GBS, following the 2009 H1N1 influenza vaccination.

Syncope (Updated)

- Syncope, or fainting, has been reported after vaccination with any vaccine, and is common among adolescent patients. Falls, as a result of fainting after vaccination, can sometimes result in serious injuries.

- Such injuries can be prevented by assuring that the vaccinated person is sitting in a chair or lying down and is observed for 15 minutes following vaccination.

Recent Adverse Event Reports in the Media

This week, a very rare adverse event following seasonal influenza vaccine was reported to VAERS and received attention by the media.

- CDC can confirm this case was reported to the Vaccine Adverse Event Reporting System (VAERS). VAERS is a useful early warning public health system that helps CDC and FDA detect possible adverse events, or side effects, following vaccination.

- Dystonia is a rare neurological condition that can be brought on by infections, brain trauma or reaction to medication. It causes body jerks and abnormal or repetitive movements.

- VAERS data, which dates back to 1991, contains 5 reports of dystonia after the administration of almost one billion doses of flu vaccine (nasal and injectable). A total of 50 cases have been reported for ALL vaccines.

- When reviewing data from VAERS, please keep in mind the following limitations:

    - VAERS is a passive reporting system, meaning that reports about adverse events can be submitted voluntarily by anyone, including healthcare providers, patients, or family members. Because of this, VAERS data may and often does include incorrect and incomplete information.

    - Underreporting, or failure to report events, is also one of the main limitations of VAERS. Serious medical events are more likely to be reported than minor ones.

- Most importantly, **VAERS cannot determine cause-and-effect**. The report of an adverse event to VAERS does not confirm that a vaccine caused the event. It only confirms that the event occurred sometime after vaccine receipt. No proof that the event was caused by the vaccine is required in order for VAERS to accept the report.

- VAERS accepts all reports without judging whether or not the event was caused by the vaccine. No reports are deleted out of the VAERS system. Therefore, it is possible to have more than one report on an individual case.

- As with all serious reports of adverse events, VAERS staff collect follow-up records on each case and medical officers review them closely to determine if in-depth reviews are needed before conducting additional studies.

- VAERS defines "serious adverse events" as those involving death, hospitalization, life-threatening illness, persistent or significant disability/incapacity, or certain other medically-important conditions.

- The most reliable information about vaccine side effects can be found in the manufacturer's vaccine package insert, vaccine information statements (VISs), or the ACIP's statements on vaccines at http://www.cdc.gov/vaccines/pubs/ACIP-list.htm.

Seasonal Influenza Vaccine

- Two systems that look at seasonal influenza vaccinations administered and billed show that many more individuals have been vaccinated this season than at the same time last year. This is most likely due to the early availability of vaccine.

- Recently there have been several media reports describing unpublished findings from seasonal influenza vaccine studies conducted in Canada suggesting that receipt of the 2008-09 seasonal influenza vaccine (given last influenza season) was a risk factor for developing influenza caused by the 2009 H1N1 virus.

- Preliminary results of studies conducted in the United States using methods similar to the Canadian studies did not indicate that receiving a seasonal influenza vaccine increased the risk of developing influenza caused by the 2009 H1N1 influenza virus.

- In addition, no other country has reported that seasonal influenza vaccine increases the risk of developing influenza caused by the 2009 H1N1 influenza virus.

- For more information on CDC's response to this study, visit http://www.cdc.gov/media/pressrel/2009/s091007.htm and http://www.cdc.gov/h1n1flu/vaccination/public/vaccination_qa_pub.htm#canadian .

- CDC continues to recommend seasonal flu vaccination. Currently the vast majority of influenza being reported to CDC is 2009 H1N1. Influenza is very unpredictable but CDC expects both 2009 H1N1 flu and seasonal flu to cause illness, hospital stays and deaths this season.

Seasonal Influenza Vaccine Supply and Distribution

- While the national picture reveals good supply and rapid distribution, local areas may not have received as much vaccine as they anticipated at this point in the season and providers seeking additional vaccine now may be unable to purchase it. For more information about seasonal supply, please refer to IVATS (http://www.preventinfluenza.org/ivats/) over the coming weeks.

- The largest supplier of seasonal flu vaccine, Sanofi Pasteur is experiencing a delay in their shipments. Currently, the company has shipped more than half of the 50.5 million doses of Sanofi Pasteur seasonal flu vaccine ordered by U.S. health care providers. It could be November before customers receive their complete orders.

- CDC is working with manufacturers, states, and immunization providers to identify existing seasonal flu vaccine and get it to providers who can administer it to people who need and want it.

- Most will be able to obtain vaccine from their usual provider, but some will have to obtain the vaccine from an alternative provider

- As of 10/9/09, 82 million doses of seasonal influenza vaccine have been distributed (this is about 71% of doses expected this season).

- At the current time, five influenza vaccine manufacturers are projecting as many as 114 million doses of seasonal influenza vaccine will be available from currently licensed manufacturers in the United States for use during the 2009-10 influenza season.

- Manufacturers project producing approximately 50 million doses of thimerosal-free, or preservative-free, seasonal influenza vaccine.

- Manufacturer projections indicate that the vast majority of vaccine will be distributed by the end of October. However, some vaccine distribution

may continue into November, including doses that are ordered during the fall.

- 2009 H1N1 vaccine production efforts currently underway are being carried out in such a way to minimize any impact upon the total amount of seasonal vaccine available. In fact, the timing of 2009 H1N1 vaccine production, as directed by the federal government, was designed to allow sufficient time for manufacturers to be able to carry out their planned production of seasonal influenza vaccine.

- Despite vaccine production estimates that exceed past usage, providers seeking to order vaccine currently and during the past several weeks have experienced challenges in doing so. There are several reasons for these challenges. First, in early June, one of the manufacturers adjusted down their seasonal flu vaccine estimates, which resulted in some customers switching prebooks to other products. These switches reserved unprebooked vaccines that were still available for order, making doses that are normally available for order during the summer and early fall months no longer available. Second, there may be more providers seeking to purchase vaccine at this time of year than normally occurs due to (1) recent 2009 H1N1 disease and related coverage in the media that may have increased the demand for seasonal flu vaccination, and (2) a desire to complete seasonal flu vaccination efforts in advance of 2009 H1N1 vaccination efforts to the extent possible.

- As in past seasons, availability of seasonal vaccine may change as the season progresses because some prebooks do not materialize into purchases. Providers looking to order additional vaccine should be encouraged to use the supplies that they have now and continue to look for additional flu vaccine for purchase in the coming weeks.

- To assist providers in finding flu vaccine available for purchase, the National Influenza Vaccine Summit supports IVATS, the Influenza Vaccine Availability Tracking System, which provides information about vaccine manufacturers and distributors with vaccine available for purchase. IVATS can be found at: http://www.preventinfluenza.org/ivats/. The information in IVATS is updated throughout the influenza vaccination season.

- CDC's seasonal influenza web site is at http://www.cdc.gov/flu with a new design, the latest information updates, and free resources.